UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG,

Plaintiff,

-vs.-

GNOSIS S.P.A. and
GNOSIS BIORESEARCH S.A.,

Defendants.

Case No. 07 Civ. 5898 (RJS)(JCF)

GNOSIS' TRIAL MEMORANDUM

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I. INTRODUCTION

On its most basic level, this case presents a dispute over the letter L as it is used in stereochemical nomenclature. Through this action, Merck seeks a judicial mandate that use of the letter L in the acronym "L-5-MTHF" or abbreviation "L-5-Methyltetrahydrofolic acid, calcium salt" is only appropriate to describe the spatial configuration of reduced folates at the carbon 6 position of the pteridine section of the folate molecule. Merck suggests that Gnosis' use of the acronym and abbreviation to identify its compound, "N-[4-[[2-amino-5-methyl-1,4,5,6,7,8-hexahydro-4-oxo-(6 R,S)-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid calcium salt" ("6RS Product"), is improper since the product is a mixture of two diastereoisomers and not a pure isomer. But the leading authorities in stereochemical nomenclature endorse Gnosis' use of the letter L to describe the glutamic acid section of the molecule. Merck's problem is that it has expended a substantial amount of time and resources on a marketing campaign designed around its own incorrect use.

In essence, Merck is asking this Court to choose between conflicting scientific naming conventions, a task ill suited for a District Court. Stereochemical nomenclature for nutritional supplement components should be dictated by experts in the field – not the judiciary. For this Court to determine that Gnosis' use of a particular letter, acronym or chemical term is false, and that Merck's conflicting use is unambiguously true, would require this Court to dictate technical, scientific standards for the titling of ingredients and product chemical labeling in an area where nomenclature experts, food scientists and organic chemists have not yet reached a consensus.

As will be shown, Gnosis' use of the letter L in the abbreviation L-5-Methyltetrahydrofolic acid, calcium salt and the related acronym L-5-MTHF is appropriate under the current prevailing guidelines for stereochemical nomenclature and is not literally false. Moreover, Gnosis' labeling is not impliedly false because there is no likelihood that the "consumers" for Gnosis' product would be confused, particularly in light of their sophistication as manufacturers and sellers of dietary supplements which incorporate the reduced folate ingredient and do not purchase ingredients based on acronyms. These customers also receive technical product literature identifying the precise constituents of the product purchased and, in the

exercise of reasonable care, base their purchasing decisions on the full chemical name and specifications for the ingredients. In an effort to satisfy its burden of proving that a substantial portion of the intended audience was confused or likely to be confused by Gnosis' labeling, Merck offers *de mimimis* anecdotal evidence it claims suggests confusion among actual customers. But isolated incidents of debatable confusion do not come close to satisfying Merck's burden of proving that Gnosis' labeling is deceptive because a ***substantial portion*** of the commercial audience was confused.

Finally, Merck has not been, and is not likely to be, injured by Gnosis' use of a scientific naming convention different from Merck. Merck has not lost sales and the allegedly offensive labeling was discontinued more than two years ago. Moreover, Merck does not manufacture a 6RS Product and the two companies do share the same economic customer base. Several of Gnosis' customers were terminated by Merck for failing to meet minimum purchasing requirements. As a result, Merck cannot satisfy the elements of its false advertising claims. This lack of causation is demonstrated because, after Gnosis stopped using the "L" in its lableing, Gnosis' sales dramatically increased.[1] Merck must explain how Gnosis' cessation of using the "L" in its nomenclature actually caused more customers to buy its product.

II. FACTUAL BACKGROUND

A. The Parties' Respective Products and Nature of the Dispute

Merck is a Swiss corporation which provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications. Merck manufactures and distributes N-[4-[[2-amino-5-methyl-1,4,5,6,7,8-hexahydro-4-oxo-(6S)-pteridinyl)methyl]amino]benzoyl]-Lglutamic acid calcium salt ("6S Product"), which is a substantially pure, nutritionally active isomer for use in dietary supplements, which Merck sometimes refers to by the

[1] Gnosis came to learn over the 2-3 years it sold the 6RS Product, that there was great confusion in the marketplace over nomenclature. Partly to avoid this confusion, partly to get Merck off its back, but never agreeing with Merck that the Merck nomenclature was the "one and only," Gnosis dropped the "L" from all of its literature.

acronym "L-5-MTHF." Merck's product is sold under the registered trademark "Metafolin." Since 2002, Merck has spent millions of dollars marketing its Metafolin brand.

Gnosis is an Italian biotechnology company which specializes in the manufacturing and sales of fermentation raw materials and natural finished products used in the pharmaceutical, nutraceutical, cosmetic, veterinary, and agricultural industries. In 2004, Gnosis purchased a plant in Sant' Antonio, Switzerland from Abbott Knoll Bioresearch ("Abbott"). At the time, Abbott had an expired patent on a 6RS Product, a dietary ingredient which was a 50/50 mixture of two different diastereoisomers. Prior to Gnosis' purchase of the Abbott plant, Abbott had been producing its 6RS Product for several years. In 1998, GNC had submitted a New Dietary Ingredient Notification ("NDI") to the FDA in the U.S. for the Abbott 6RS Product and the FDA indicated no objection to the product in terms of safety. This approval confirmed for Gnosis that the product was safe and inspired Gnosis to move forward with developing a similar product. Armed with Abbott's expired patent and its plant and equipment, Gnosis began development of a 6RS Product in 2005. Gnosis' production facility was licensed by Swissmedic in July 2005 for active pharmaceutical ingredients ("API") manufacturing. By early 2006, Gnosis reached a point where it could produce samples and also had the capability to produce commercial quantities of a 6RS Product. Gnosis' R&D also concluded that a 6S Product could be produced commercially.

By early 2006, Gnosis had developed its 6RS Product, which it later branded under the name "Extrafolate." Although Gnosis was aware of the market demand for the 6RS Product, it initially only produced a few small samples of the 6S Product (branded Extrafolate S), to investigate market demand. In March 2006, Gnosis presented samples of both its Extrafolate and Extrafolate S products at the Natural Expo West trade show in Anaheim, California. At this tradeshow (and each subsequent year at both the Anaheim and Las Vegas trade shows), Gnosis' booth and written materials advertised both its 6RS and 6S Products. Gnosis' representatives informed all potential customers that Gnosis could manufacture raw materials for either product. Among the marketing materials available at each tradeshow was a product specifications sheet and pricing for both products. The product specifications sheet from the very first

version included the full chemical name for each product. And it was clear that Gnosis' 6S Product was almost 3 times as expensive as its 6RS Product.

Gnosis sells its products solely to manufacturers and distributors of nutritional supplements who buy the products in order to formulate their final products with other ingredients (vitamins, amino acids, salts, etc.) in different forms. The final products are sold under the respective manufacturers' company names and labels through the big distribution channels. Critically, Gnosis does not sell directly to the end consumers of those supplements.

At the time Gnosis entered the market, Merck was the only company selling a 6S Product and, since the time Abbott stopped selling its 6RS Product, there was no company selling the 6RS Product in the U.S. Gnosis' US distributor informed Gnosis that there was little demand for the 6S Product, due mainly to the higher relative price. Thus, market demand led Gnosis to focus on commercialization of its 6RS Product, rather than the 6S Product. Notwithstanding, Gnosis continued to offer both products for sale in the United States. But it was not until April 2009 that Gnosis actually sold any of its 6S Product.

Between March 2006 and March 2009 Gnosis labeled its 6RS Product with the abbreviation "L-5-Methyltetrahydrofolic acid calcium salt," or the acronym "L-5-MTHF." This choice of labeling was based, in part, on a U.S. patent by Knoll Bioresearch, a predecessor of Abbott. The patent used the name "(±)-L-5-formyl-5,6,7,8-tetrahydrofolic acid" to describe the 6RS Product. In addition, Gnosis' long-term technical consultant, Professor Valoti, confirmed that under the prevailing naming convention for folates, Gnosis' labeling for its 6RS Product was proper and that Gnosis could further eliminate the (+/-) designation because, if it is not stated, the product is understood to be a mixture.

Almost immediately after entering the market in mid-2006, Merck (consistent with its reputation for intimidating emerging competitors with litigation) quickly sent Gnosis and several of its U.S. and European agents a "cease and desist" letter claiming that Gnosis' 6RS Product "might" be infringing on Merck's patent. After nearly a year, Merck changed its course. Merck now claims that Gnosis' ***past*** use of the abbreviation L-5-Methyltetrahydrofolic acid calcium salt, and the acronym L-5-MTHF, to describe its

6RS Product constitutes false advertising and that the only appropriate use of the abbreviations is to describe the 6S Product. Thus, the resolution of this case requires an analysis of the appropriate nomenclature for chemical compounds.

B. The Chemistry at Issue and Various Naming Conventions

Stereochemistry is an area of chemistry that deals with the 3-dimensional structure and properties of molecules. Stereoisomer refers to molecules, which are related in chemical formula and connectivity but which manifest different structures. A diastereoisomeric mixture is a mixture of at least two diastereoisomers. The diastereoisomers that make the diastereoisomeric mixture are integral parts of the whole. Folates like the products at issue in this litigation are comprised of two segments: a pteridine ring and an amino acid. The amino acid segment in the folate family is glutamic acid.

Various naming conventions exist to distinguish the various stereoisomers from one another. Each convention has its own significance and has no direct relation to the others. Early naming conventions designated molecules which rotate the plane of polarized light in the clockwise direction with a "(+)" or "d" (for dextrorotatory), while molecules which rotate the plane of polarized light in a counter-clockwise direction are designated with a "(-)" or "l" (for levorotatory). Corresponding isomers are often referred to as the (+)-isomer and the (-)-isomer. Additionally, use of the chemical name with no symbol(s) indicates a mixture of different stereoisomers.

To address the confusion created by the (+/-) and d/l designations (since derivatives could have either optical rotation), in the late 1800's Hermann Emil Fischer introduced the use of the capital letters "L" and "D" to indicate the stereochemistry of a molecule ("Fischer-Rosanoff convention"). Under the Fischer-Rosanoff convention, the particular prefix, D or L, is based on their relation to glyceraldehyde.[2]

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[2] Configurations with the same relative configuration as (+)-glyceraldehyde are assigned the D prefix, and those with the relative configuration of (-)-glyceraldehyde have the L prefix. It is significant that the basis for this system is that the molecule being described has a genetic relationship to glyceraldehyde.

In 1966, Cahn, Ingold and Prelog created a new set of rules to name stereoisomers of a molecule using the letters "R" and "S" ("Cahn, Ingold, Prelog" or "CIP"). Following the Cahn-Ingold-Prelog rules, priorities are assigned to the substituents of a chiral carbon and an R or an S is assigned to the configuration at that carbon. The R and S designations are most commonly used to describe stereochemical configurations. Both the Cahn, Ingold, Prelog system and the Fischer-Rosanoff system are still used today. Presently, there is no single convention that is uniformly and consistently used throughout chemical literature.[3]

C. Efforts to Promote Uniformity in Naming

1. IUPAC Standards

The International Union of Pure and Applied Chemistry (IUPAC) is an international organization recognized for providing global standards for the naming of chemical compounds and terms for describing their characteristics, including stereochemistry. In 1996, in an effort to promote uniformity, the IUPAC published a document entitled, "Basic Terminology of Stereochemistry" (IUPAC Recommendations, G.P. Moss, Pure Appl. Chem., 68, 2193-2222 (1996)) which has become a worldwide standard in the field of stereochemistry nomenclature. A special IUPAC supplement, "Nomenclature and Symbols for Folic Acid and Related Compounds," (DX20 "IUPAC Folic Acid Nomenclature Supplement") is devoted to the naming of Folic acids and derivatives and has been adopted by many scholarly journals.

In the IUPAC Folic Acid Nomenclature Supplement, stereochemical issues are discussed and referred back to sections on stereochemical terminology (DX12), carbohydrate nomenclature (DX31), and amino acid nomenclature (DX19). For the specification of configuration at general stereocenters, IUPAC recommends utilization of the Cahn, Ingold, Prelog convention for assigning R/S symbols. However, for the specification of sugars and amino acids, IUPAC recognizes that the Fischer-Rosanoff convention is

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[3] There is no unique correlation between the Fischer-Rosanoff convention D/L system and the Cahn, Ingold, Prelog R/S system, thus it is impossible to know the Cahn, Ingold, Prelog configuration from the Fischer-Rosanoff configuration without consideration of the stereostructure de novo.

"still in use" for assigning D/L symbols.[4]

Based on IUPAC nomenclature guidelines, because the glutamic acid in Gnosis' 6RS Product is an amino acid, Gnosis' use of the Fischer convention to describe the configuration of the glutamic acid by the letter "L" is appropriate and reasonable. Thus, the use by Gnosis of the name L-5-MTHF would ***not*** reasonably be interpreted as a reference to the essentially enantiomerically pure isomer (6S Product). Instead, in the context of folate chemistry and IUPAC guidelines, the term L-5-MTHF would reasonably be interpreted as referencing a composition of two diastereomers, (6S) and (6R).

2. The American Chemical Society's CAS Registry

The American Chemical Society ("ACS") is the world's largest society for chemical professionals. ACS publishes the CAS Registry, which is an integrated, comprehensive source of chemical information from a full range of disclosed material including patents, journals, and reputable web sources. The ACS CAS Registry permits the use of the letter L in "L-glutamic acid" to refer to the glutamic acid segment of the 6RS Product. The CAS Registry for the 6RS Product uses the term "L-glutamic acid" as a reasonable abbreviation for the 6RS Product.

The ACS CAS Registry's usage of "L" to refer to the configuration of the glutamic acid segment of the 6RS Product, supports the reasonableness of Gnosis' use of the Fischer-Rosanoff system to describe the configuration of the glutamic acid in the 6RS Product by the symbol "L."

Several published patents in which the glutamic acid section of the molecule is identified with the capital letter "L" consistent with Gnosis' use will also be introduced at trial.

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[4] One modern comprehensive text in the area of stereochemistry is "Stereochemistry of Organic Compounds," by Ernest Eliel and Samuel Wilen (Wiley Interscience 1994) ("Eliel Text"). The Eliel Text states that the letters D/L are "configurational descriptors for carbohydrates or alpha amino acids. See chapter 5. Their use for other kinds of chiral compounds is obsolete." Another seminal text, entitled "Advanced Organic Chemistry," 2nd Ed. by G.W. Wheland, John Wiley & Sons. NY,1949, discusses the confusion even in the scientific community regarding the nomenclature.

D. Gnosis' Labeling and "Intended Audience"

From March 2006 to April 2009, Gnosis used the acronym L5 MTHF to refer to its 6RS Product in its Product Specifications sheets, Certificate of Analysis, Material Safety Data Sheets and packaging labels. From March 2006 to April 1, 2009, Gnosis also used the abbreviation "L-5-methyltetrahydrofolic acid, calcium salt" on its Product Specifications, Certificates of Analysis and MSDS for its 6RS Product. Critically however, during this same time period, the Product Specifications and Certificates of Analysis also contained the indisputably correct full chemical name for the 6RS Product.[5] Starting in September 2006 Gnosis began using a marketing brochure that makes multiple references to the 6RS Product as "6[R,S] 5-MTHF," and referenced the diastereomeric mixture. As set forth above, Gnosis' customers and potential customers are manufacturers and distributors of nutraceutical products not end users. Generally, these manufacturers have background and training in nutraceuticals and often have a background in science and chemistry. These manufacturers are currently required by the FDA to test or examine their dietary ingredients to verify their identity. 21 C.F.R. § 111.75 (2007).

Each year since 2006, Gnosis' booths at the annual industry trade shows were visited by hundreds of potential customers. Gnosis also marketed its products via its website and directly through power point presentations and in-person visits to potential customers. Gnosis provided its potential customers with its marketing literature advertising both its 6RS and 6S Products. Further, Gnosis was (somewhat unsuccessfully) marketing a 6S Product although demand was almost nonexistent since the 6RS Product was one third of the cost. Gnosis' potential customers did not require chemistry or mathematics degrees to understand the economics at play.

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[5] It should be noted that, although abbreviations and acronyms are inherently ambiguous, ***the complete chemical name of the subject compound is not in dispute.*** The only "L" in that complete, lengthy, complex chemical name is a clear and unmistakable reference to the stereochemistry of the glutamic acid. No expert in this case, on either side, would dispute this universal proposition. In contrast, the letters R and S in the full chemical name or likewise a clear and unambiguous reference to the stereochemistry of the pteridine ring. Gnosis' abbreviation is entirely faithful to the nomenclature for the longer chemical name according to all experts.

Beginning March 26, 2009, Gnosis stopped using the abbreviation "L-5-methyltetrahydrofolic acid, calcium salt" or the acronym "L-5-MTHF" to describe its 6RS Product and began exclusively referring to its 6RS Product as "Extrafolate" with the full chemical name.

III. GNOSIS' LABELING DID NOT VIOLATE SECTION 43(a) OF THE LANHAM ACT

In order to establish a Lanham Act claim based on a false or misleading representation of a product, the plaintiff must prove: (1) that the defendant has made false or misleading statements as to his own product [or another's]; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the advertised goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *Werner-Lambert Co. v. Brathasure, Inc.*, 204 F.3d 87, 92 (3d Cir. 2000) (citing *Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Rhone-Poulenc Rorer Pharmaceuticals, Inc.*, 19 F.3d 125, 129 (3d Cir.1994)).

A. Merck Lacks Standing to Bring its Lanham Act Claims

The logical starting point is whether Merck satisfies the requisite standing requirements. To establish standing to pursue a false advertising claim under section 43(a)(1)(B), an aggrieved party must demonstrate both (1) "'a reasonable interest to be protected against the advertiser's false or misleading claims,'" and (2) "'a reasonable basis for believing that this interest is likely to be damaged by the false or misleading advertising.'" *Societe Des Hotels Meridien v. LaSalle Hotel Operating P'ship*, 380 F.3d 126, 130 (2d Cir.2004) (quoting *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir.1994)). Where a plaintiff's products are "not obviously in competition with the defendant's products, [and] the defendant's advertisements do not draw direct comparisons between the products," a plaintiff must make a "more substantial showing" of "injury and causation" to satisfy the reasonable basis prong of the standing requirement. *Ortho Pharm. Corp.*, *supra*, 32 F.3d at 694.

This is not a case where Gnosis drew any comparison with Merck's product through its labeling. In fact, Gnosis's labeling merely identified the dietary ingredient by its full chemical name and added an

acronym or abbreviation for a short period.[6] Although both Merck and Gnosis sell dietary ingredients, the two companies cannot fairly be considered "competitors" in the relevant economic market since their respective intended audiences differ wildly in economic position. Gnosis' customers simply cannot afford Merck's products.[7] Even Merck's own key personnel testified that the parties are not competitors. Katz Depo., 191:12-192:5; Weibel Depo., 22:10-23:8. Because the parties do not share the same economic customer-base, and because Merck has lost no sales of its 6S Product as a result of Gnosis' labeling of its 6RS Product, Merck cannot demonstrate any injury which was caused by the allegedly offensive labeling. As a result, Merck lacks "prudential" standing for its Lanham Act claims.

Before a court can even reach the issue of "prudential" standing under the Lanham Act, it must first address the issue of standing under Article III of the Constitution. "Standing is an essential and unchanging part of the case-or-controversy requirement of Article III." *Ford v. NYLCare Health Plans of Gulf Coast, Inc.*, 301 F.3d 329, 332 (5th Cir. 2002) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Courts have stated:

> The irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an 'injury in fact'-an invasion of a legally protected interest which is (a) concrete and particularized ... and (b) actual or imminent not conjectural or hypothetical ... Second, there must be a causal connection between the injury and the conduct complained of ... Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Ford, supra, 301 F.3d at 332; *Lujan, supra*, 504 U.S. at 112; U.S.C.A. Const. Art. 3, § 2, cl. 1.

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[6] This Court has already dismissed Merck's counts alleging that Gnosis was holding its own products out as though they were Merck's. In dismissing Counts III and IV of the First Amended Complaint, this Court specifically found that Merck lacked any evidence that consumers believed they were purchasing Merck's product when they bought Gnosis' product. Memorandum and Order of the Honorable Richard J. Sullivan, District Judge dated March 17, 2011, p. 9-10.

[7] As discussed below, the best evidence of the financial disparity between the parties' respective customers is the fact that several of Merck's former customers only came to Gnosis after being terminated by Merck for failing to meet its minimum purchasing requirements. And, Merck refused to sell to at least one Gnosis customer because it did not have the financial wherewithal to meet Merck's minimum purchasing requirements. Gnosis could not have deprived Merck of customers which Merck refused to sell to.

Plaintiff bears the burden of proving all three elements and the failure to establish any one deprives the federal courts of jurisdiction. *Ford, supra*, 301 F.3d at 332 (citing *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir.2002)).

Merck cannot demonstrate either actual or imminent "injury" from Gnosis' prior use of a different stereochemical naming convention than that urged by Merck. To date, Merck has failed to produce any evidence that it has lost any sales or customers as a result of Gnosis' labeling. Gnosis' customers cannot afford to purchase from Merck. And, the allegedly offensive labeling ceased in March 2009. Thus, there is no ***immanent*** threat of harm to Merck. At best, Merck's alleged injury can only be fairly described as conjectural or hypothetical, insufficient to establishing Article III standing, let alone prudential standing.

B. Merck Cannot Demonstrate Falsity

To establish the element of "falsity" under the Lanham Act, the plaintiff must prove that (l) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse customers. *S. C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001); *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010). Under either standard, Merck is unable to satisfy its burden of proof that Gnosis' past labeling for its 6RS Product was false or misleading.

1. Gnosis' Labeling Was Literally Accurate

Under the literal falsity theory, Merck has the burden of proving that the challenged advertisement is "false on its face" or "explicitly false." *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 348 F. Supp. 2d 165, 178 (S.D.N.Y. 2004). However, Gnosis' use of the abbreviation L-5-Methyltetrahydrofolic acid calcium salt, and the related acronym L-5-MTHF is literally true and is the most scientifically accurate way to describe the 6RS Product. Gnosis' use of the letter L to describe the glutamic acid section of the molecule is consistent with IUPAC's recommendations on stereochemical nomenclature

for the specification of sugars and amino acids.[8]

Further, only an unambiguous message can be literally false – if the language is susceptible to more than one reasonable interpretation, the advertisement cannot be deemed to be literally false. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, IS8 (2d Cir. 2007). Accordingly, even if the Court declines to accept IUPAC recommendations for naming protocol, Merck is left with the burden of proving, by a preponderance of the evidence, that IUPAC's recommended naming protocol is ***unambiguously*** wrong.

Merck offers the opinion of food science and organic chemistry "experts" to suggest, at best, that Gnosis' naming protocol is unconventional – not that it is unambiguously false. And, Merck had trouble even finding experts willing to go that far.[9] By contrast, Gnosis offers the opinion of one of the leading names in stereochemical nomenclature, Professor Jay Siegel, who is a 24 year professor of Chemistry and was a member of the working committee which drafted the IUPAC's "Basic Terminology of Stereochemistry." Having helped "write the book" on stereochemical nomenclature, Professor Siegel, opines that Gnosis' use of the "L" in L-5-MTHF and L-5-Methyltetrahydrofolic acid, calcium salt to refer to the configuration of the glutamic acid in its 6RS Product is in accordance with the IUPAC guidelines on limiting use of the D/L nomenclature to refer amino acids. Because the glutamic acid in the 6RS Product is an amino acid, Gnosis' use of the Fischer-Rosanoff convention to describe the configuration of the glutamic acid by the letter "L" is reasonable and cannot be considered explicitly false. According to Professor Siegel, the L-5-MTHF acronym would not reasonably be interpreted as a reference to Merck's essentially enantiomerically pure 6S Product. Thus, although it is not Gnosis' burden, the evidence will demonstrate that it is Merck's use of the abbreviation and acronym that is false, not Gnosis' use.

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[8] Merck argues that, since in all folates the configuration of the glutamic acid section of 5-methyltetrahydrofolate is in the L configuration, it need not be stated at all. But this proposition does not lead to the conclusion that it would be false to expressly state the L.

[9] Merck's own documents include email correspondence from October 2007 where Merck was informed by at least one expert, Dr. Barry Shane of U.C. Berkeley (who Merck declined to designate for obvious reasons), that the "L" in L-5-Methyltetrahydrofolic acid, calcium salt refers to the L-glutamate consistent with Gnosis use. (DX69.)

Notwithstanding, the irony that the entire premise of Merck's false advertising claim is itself false cannot be understated.

2. Gnosis' Labeling is Not Impliedly False

Absent literal falsity, to prove the falsity Merck must instead establish that the challenged statements are likely to mislead or confuse consumers. *Johnson & Johnson* Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992). To do so, Merck must demonstrate that "a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement." *Id.* at 297-298. While there is no magic number or percentage who must be mislead, the number has been characterized in terms of "statistically significant," "significant portion," or "a substantial proportion." 5 McCarthy on Trademarks and Unfair Competition § 27:57 (4th ed.).

In the Second Circuit, the success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a customer survey. *Smithkline Beecham Corp., supra,* 960 F.2d at 298; *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F.Supp.2d 339, 345 (S.D.N.Y. 2008). While survey evidence is not required, it has become so widely recognized as the most probative evidence of confusion that the failure to offer a survey "counts against finding actual confusion." *O'Keefe v. Ogilvy & Mather Worldwide, Inc.*, 590 F.Supp.2d 500, 523-524 (S.D.N.Y. 2008) (quoting *Merriam-Webster, Inc. v. Random House, Inc.*, 35 F.3d 65, 72 (2d Cir.1994). The reason survey evidence is particularly probative is that surveys employ "'filters' to screen out individuals whose responses may distort the results; the questions are directed to 'the real issues'; and the questions are not leading or suggestive." *Procter & Gamble Co., supra,* 574 F.Supp.2d at 345-346 (citations omitted.) The use of a control group enables the Court to distinguish between pre-existing consumer beliefs and the beliefs which were the result of the advertising. *Id.* at 351.

In this case, Merck has opted not to commission a survey to satisfy its burden and instead relies on the anecdotal on deposition testimony of five alleged Gnosis customers. Absent the safeguards imposed by a survey (non-leading questions and no relation to litigation), the deponents exhibited moments of confusion in response to the leading (and often confusing) questions of Merck's counsel posed during a

pressure-packed deposition. However, the foundation for the relevant confusion is an ability to understand the difference between the truth and error, something Merck failed to prove. For example, the witnesses selected by Merck confessed either that they did not understand the difference between the two products or that in spite of their confusion regarding the abbreviations; they understood fully what they were purchasing. For various reasons, the evidence is insufficient to establish that a ***statistically significant*** portion of the intended audience was confused or likely to be confused.

3. Merck's Confusion Evidence is Unreliable and Insufficient

It is undisputed that Merck has engaged in an expensive marketing campaign which identifies its pure isomer by the abbreviation L-5-Methyltetrahydrofolic acid calcium salt and the acronym L-5-MTHF. Merck voluntarily chose this nomenclature ***inconsistent*** with the prevailing standards for its marketing campaign.[10] It has since saturated the market with its incorrect labeling, creating confusion in the industry. Thus, absent a consumer survey, it cannot be determined whether Merck created the confusion.

In Merck's email communications soliciting potential expert witnesses, Merck even acknowledged that: "Currently there is a disagreement regarding the name 'L-5-Methyltetrahydrofolic acid, Calcium salt'. We are aware of the fact that this name is not unambiguous but nevertheless we would like to ask you whether you could tell us which chemical structure you would spontaneously assign with this name." DX68 at Eprova0001034. In response, one of Merck's retained experts in this case, Dr. Jesse Gregory, conceded that the terminology is ambiguous, stating, "[f]rom the viewpoint of chemical nomenclature, L-5-methyltetrahydrofolic acid is an ambiguous term." *Id.* at Eprova0001034.

As previously mentioned, when Merck solicited Dr. Barry Shane of U.C. Berkley, he responded to the same candid admission that the nomenclature is "ambiguous," by explaining the error in Merck's theory in this case, as follows:

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[10] For example, in Gnosis' Trial Exhibit DX67, at Eprova0000764, Merck admits that it rejected "the newer R/S-nomenclature (Cahn-Ingold-Prelog Rules)" for the "D/L-nomenclature (Fischer Projection)" for marketing reasons.

> It is my recollection that the L-nomenclature originally referred to the L-glutamate. For example, when folate analogs were synthesized, D-folate referred to pteroyl-D-glutamate. Small l and d were often used to distinguish the naturally occurring and mixed isomers obtained around the C-6 carbon of the pteridine ring before the exact configuration was known. i.e. (l)-5-methyl-THF would be the 6S isomer, (dl)-5-methyl-THF would be the mixed isomer. (+) and (-) were also used when the optical rotation of the different isomers around C-6 were known. After the structures of the different isomers were determined, it became usual practice to use 6S-5-methy-THF for the natural form of methyl folate.

DTX69 at Eprova0001036 (Confidential - Attorneys Eyes Only).

Thus, Merck's use of the labels at issue for its 6S Product has no basis in science and is purely based on marketing. Of the scientific articles produced by Merck in this action to support its use of the terms to describe a pure isomer, most follow the Cahn, Ingold, Prelog S/R naming convention in accordance with IUPAC's recommendations. This begs the question of whether Merck can ever demonstrate implied falsity when it is Merck itself that created confusion through its own inaccurate, marketing-based use of a descriptive scientific term. The "false belief" in this case is that L-5-MTHF unambiguously and solely refers to the ***pure isomer***, not the mixture. But Merck is seeking a judicially-sanctioned monopoly on its own misuse of the technical abbreviation for a scientific term. Such a standard should not be dictated by the Court, based solely on the marketing campaign of an industry giant.

Even if Merck could rely on confusion of its own making to establish implied falsity, Merck cannot prove that a ***substantial portion*** of the intended audience was indeed confused or likely to be confused. *De minimis* evidence of actual confusion does not satisfy a plaintiff's burden of "demonstrat[ing] that a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement." *Smithkline Beecham Corp., supra,* 960 F.2d at 297-98; *O'Keefe, supra,* 590 F.Supp.2d at 523-524. As set forth above, the belief that L-5-MTHF refers to the 6RS Product is not a ***false*** belief. But, even assuming arguendo that it is false, Merck has only offered the anecdotal testimony of a few individuals to attempt to satisfy its burden of demonstrating that a statistically significant percentage of the commercial audience is confused.

(a) **Merck Relies on the Wrong "Intended Audience" Denominator**

Merck argues that, based on the deposition testimony of 5 "customers," "nearly half [of Gnosis' customers]… believed that they were receiving the pure L isomer and/or were confused about the ingredient they were receiving." (Merck's Memorandum of Law in Support of MSJ, p. 17.) As the argument goes, 5 out of 12 customers, or approximately 42%, is a statistically significant ratio. But Merck's math is inherently flawed since the "intended audience" denominator should be far greater than Gnosis' few actual U.S. customers.[11]

In reality, the "intended audience" for Gnosis' product literature is vast, consisting of all manufacturers and distributors of nutritional supplements. It is this number that must be used as the denominator for determining the percentage of customers who are, or are likely to be, confused. Merck cannot have it both ways. It cannot limit the "intended audience" for Gnosis' advertisement to only a few actual U.S. customers to artificially inflate the ratio of allegedly "confused" customers yet at the same time argue that Gnosis engaged in "widespread dissemination" of its advertisement. For purposes of determining whether a statistically significant portion of the intended audience is, or is likely to be confused, the focus should properly be all potential customers exposed to the advertisement, not only a few actual "customers."[12] Accordingly, Merck's attempt to demonstrate that a statistically significant part of the commercial audience holds a false belief falls short.

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[11] And Merck agrees. Where it suits Merck, it readily admits that Gnosis's "advertising" in its product literature is presented to a vast audience at tradeshows, on the internet, via email and in-person. Yet, when attempting to quantify the percentage of the "intended audience" who is, or is likely to be, confused, Merck conveniently limits the "intended audience" to only 12 U.S. "customers" in an attempt to artificially inflate the resulting percentage. Gnosis' "intended audience" includes hundreds of potential customers of the 6RS Product in the U.S. alone. Merck implicitly concedes this point by including Nature's Value and Swanson as two of the 12 customers it counted. Gnosis does not sell directly to either Nature's Value or Swanson. Thus, Merck is not technically limiting its "intended audience" to actual customers who pay money directly to Gnosis.

[12] To limit the "intended audience" to only a few actual customers would fail to take into account the possibly thousands of potential customers who were not confused – such as those who realized that Gnosis' 6RS Product was a mixture and declined to purchase the mixture for any number of reasons unrelated to the nomenclature or even based on their correct understanding.

(b) **Merck's Confusion Evidence is *De Minimis* and Immaterial**

In *O'Keefe, supra,* the plaintiff failed to submit survey evidence of actual confusion in the marketplace, choosing instead to rely on eight anecdotal instances of customers who stated that upon first viewing the works in question they were confused as to the source of sponsorship. 590 F.Supp.2d at 524. The *O'Keefe* Court stated that because "the relevant confusion is that which affects the purchasing and selling of the goods or services in question," to be evidence of actual confusion in the marketplace, the testimony must indicate that the "confusion affected [the potential customer's] determination to purchase [plaintiff's] product." *Ibid.* The *O'Keefe* Court found that only one customer was "actually confused" since he alone based his purchasing decision in part on his confusion regarding the parties' respective marks. The *O'Keefe* Court further determined that this evidence was *de minimis* and failed to demonstrate that an appreciable number of ordinarily prudent purchasers were likely to be confused. *Ibid.* The following is a summary of the Merck's proffered "confusion" testimony:

- **John Alkire (AHD):** When asked by a customer about the percentage of active ingredient in the 6RS Product, Mr. Alkire sent one email asking Gnosis whether it was selling AHD a 50/50 or 98% product. Critically, Mr. Alkire testified that he knew he only bought the 6RS Product from Gnosis and was not confused.

- **Jerry Schlesser (Isochem):** Mr. Schlesser testified that he only bought a small sample of 6RS Product from Gnosis. He never resold the product because he was afraid of being sued by Merck for patent infringement. He also testified that although he thought he was getting the 6S Product, he would certainly have tested the product before reselling it and eliminated any confusion.

- **Ray Bartone (Aceto):** In response to suggestive questioning regarding documents which used Merck's nomenclature, Mr. Bartone testified that he believed that the letter L referred to the active isomer and the letter D referred to the inactive isomer. Notwithstanding, he clearly understood that Gnosis sold two separate products, one 50/50 mixture and one pure isomer, and could tell the difference between them from the specification sheets. Aceto's in-house PhDs asked very scientific questions about Gnosis' products prior to making any purchase. As Mr. Bartone testified, Aceto ultimately purchased both the 6RS and 6S Products from Gnosis and knew exactly what the difference was between them. Thus, any "confusion" as to the meaning of the acronym did not impact Aceto's purchasing decision.

- **Roxanne England (Swanson)/Lori Newburg (Nature's Value):** Swanson was buying Merck's Metafolin 6S Product until Merck refused to sell to Swanson's supplier, Nature's Value. Nature's Value contacted AHD and purchased a small amount of Gnosis'

> 6RS product and believed that it was purchasing the 6S Product. However, Ms. England testified that Swanson immediately ceased buying Gnosis' product once it was served with a subpoena by Merck in this litigation because, as a result, it was unsure of what the product was that it was purchasing.

To establish a false advertising claim under Section 43(a) of the Lanham Act, a plaintiff must prove the deception is material in that it is likely to influence purchasing decisions. *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F.Supp.2d 165, 178 (S.D.N.Y. 2004). Under either theory of falsity (literal or implied), materiality must be demonstrated in order to show that the misrepresentation had some influence on consumers. *Tiffany (NJ) Inc., supra*, 600 F.3d at 112; *Cashmere & Camel Hair Mfr. Inst. v. Saks Fifth Avenue*, 284 F.3d 302, 312, n.10 (1st Cir. 2002).

As it pertains to this case, Merck has not and cannot demonstrate that any confusion resulting from Gnosis' labeling is material. As emphasized above, Gnosis' customers are the dietary supplement manufacturers who are too sophisticated (and too susceptible to liability) to rely solely on an acronym in making a decision to purchase an ingredient to incorporate into its dietary supplements. To the in-house scientists in these companies, the short names or acronyms are meaningless as it pertains to their purchasing decisions.

Regardless, even in the light most favorable to Merck, only one direct customer and one potential downstream customer demonstrated any level of confusion which impacted a decision to purchase a sample of Gnosis' product. Ironically, actual product purchases by these same "confused" witnesses were thwarted by Merck's threat of litigation and issuance of a subpoena. Given the hundreds of customers and potential customers exposed to Gnosis' labeling between March 2006 and March 2009, Merck's controversial "evidence" of two instances of confusion is *de minimis* and does not satisfy its burden of demonstrating that a ***statistically significant*** part of the commercial audience is likely to be confused. Because Merck cannot demonstrate, by a preponderance of the evidence, that (1) Gnosis' labeling was deceptive and (2) that the deception impacted a customers' purchasing decision, it cannot satisfy its burden of proving a Lanham Act violation.

C. Merck Cannot Establish a Likelihood of Injury or Causation

Finally, in order to obtain injunctive relief under the Lanham Act, Merck must establish that it has been or is likely to be injured as the result of Gnosis' labeling. As set forth in detail below, Merck cannot point to actual harm from Gnosis' past labeling. And, because Gnosis stopped using the labeling more than two years ago, there exists no potential for future lost sales or loss of goodwill. As a result, Merck cannot establish a realistic "likelihood of injury" which was caused by Gnosis' labeling.

D. Merck Cannot Establish that Gnosis Acted Intentionally or Willfully

Merck describes Gnosis' labeling as "an intentionally deceptive campaign of attempting to pass off the [6RS Product] as the [6S Product]." Merck's Memorandum of Law in Support of MSJ, p. 1. But the record is devoid of evidence to support Merck's bare allegations regarding Gnosis' state of mind. The evidence establishes that Gnosis chose the labels for its 6RS Product based on science – to accurately identify the constituents of its mixture consistent with the prevailing scientific naming convention. Gnosis inherited the 6RS Product from Abbott. It labeled the product consistent with its former label and solicited the advice of its expert consultant to verify the accuracy of that label. Merck has not, and cannot establish that Gnosis' acted intentionally or willfully or that Gnosis' labeling decision was made in bad faith.

IV. MERCK CANNOT ESTABLISH VIOLATIONS OF NEW YORK LAW FALSE ADVERTISING LAWS

State law claims under N.Y. Gen. Bus. Law §§ 349(h) and 350(e)(3) are analyzed under the same substantive standards as the Lanham Act claims. See, e.g., *CIBA Vision Corp., supra*, 348 F. Supp. 2d at 178 n.6; *Novo Nordisk A/S v. Becton Dickinson and Co.*, 997 F. Supp. 470, 472 n.1 (S.D.N.Y. 1998). Additionally, the state law claims may require the plaintiff to demonstrate the defendant's bad faith or intent. *Girl Scouts of the U.S. v. Bantam Doubleday Dell Publ' g Group, Inc.*, 808 F.Supp. 1112, 1131 (S.D.N.Y. 1992). As set forth above, Merck cannot establish the essential elements of its Lanham Act claims against Gnosis and cannot demonstrate that Gnosis' choice of labeling was made in bad faith. As a result, Merck's state law claims similarly fail.

A. Merck's Section 349 Deceptive Trade Practices Claim Fails

To establish a prima facie case under New York General Business Law statutes, Section 349 a plaintiff must show: "(1) the defendant directed deceptive acts at consumers; (2) the defendant's acts mislead in a material way; and (3) an injury, as a result of the defendant's acts." *Rodriguez v. It's Just Lunch, Int'l,* 2010 WL 685009 (S.D.N.Y. Feb. 23, 2010). "Misleading" in this context has been defined by the New York courts as "likely to mislead a reasonable consumer acting reasonably under the circumstances." *Cohen v. JP Morgan Chase & Co.,* 498 F.3d 111, 126 (2d Cir. 2007). Merck cannot establish that Gnosis' labeling of its 6RS Product was misleading. As set forth above, Gnosis' use of the challenged abbreviation and acronym was literally accurate. Moreover, even assuming that the labeling could be deemed misleading, Merck cannot demonstrate that a reasonable dietary supplement manufacturer acting reasonably under the circumstances would ever base its purchasing decisions of a dietary supplement ingredient solely on an acronym or abbreviation contained on its label. Rather, in the exercise of reasonable diligence, these sophisticated customers instead rely on the full chemical name of the ingredient coupled with testing performed on samples. Thus, the intended audience was not "materially" mislead.

Finally, Merck must demonstrate "actual" harm resulting from Gnosis' labeling. *See, Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26 (N. Y. 1995) ("[A] plaintiff seeking compensatory damages must show that the defendant engaged in a material deceptive act or practice that caused actual, although not necessarily pecuniary, harm."). As set forth herein, Merck has no evidence of any lost sales and there is no likelihood of future injury since the offending labeling has long since been discontinued. Thus, Merck's deceptive trade practices claim under Section 349 fails.

B. Merck's Section 350 False Advertising Claim Fails

A claim of false advertising under Section 350 requires all of the same elements as a claim under Section 349. Additionally, unlike a claim brought under Section 349, section 350 requires proof of actual reliance. *Rodriguez, supra,* 2010 WL 685009 at *10. Thus, Merck must prove that it has relied to its detriment. See, *Pelman ex rel. Pelman v. McDonald's Corp.,* 396 F.3d 508, 510-11 (2d Cir. 2005).

As stated immediately above, Merck cannot establish the three elements required by Section 349 and, as a result, cannot state a claim under Section 350. Further, there is no evidence that Merck relied in any way on Gnosis' labeling to its detriment. Indeed, the opposite conclusion is warranted. As set forth below, immediately upon Gnosis' entry into the U.S. market in 2006, Merck initiated its campaign of scorched-earth litigation to prevent Gnosis from competing in the marketplace by threatening to sue Gnosis and its distributors and customers for first patent infringement and, later, false advertising. There was no point where Merck was mislead by, or relied to its detriment on the accuracy of, Gnosis' labeling. Thus, injury to Merck resulting from its reliance on Gnosis' labeling simply cannot be demonstrated.

V. THIS CASE PRESENTS A NON-JUSTICIABLE CONTROVERSY

The gravamen of Merck's claims is that Gnosis allegedly mislabeled the 6RS product L-5-MTHF. Merck's First Amended Complaint accuses Gnosis of failing to "follow the … language that has been approved by the FDA." First Amended Complaint, ¶35. Merck further references documents filed with, and allegedly approved by, the FDA pursuant to FDCA regulations. First Amended Complaint, ¶¶ 10, 35.

The Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq., governs the labeling requirements for ingredients in dietary supplements such as Gnosis' 6RS product. See, e.g., 21 U.S.C. § 343(a)(l). Various regulations promulgated in connection with the FDCA also provide specific guidance regarding labeling requirements for ingredients in dietary supplements. See, e.g., 21 CF.R. §§ 101.9, 101.36. Thus, on its face, the First Amended Complaint appears to be an attempt to enforce the FDCA regulations. To that extent, the Court may properly refuse to recognize Merck's claims since the FDCA affords no private right of action.[13]

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[13] See, e.g., *In re Epogen & Aranesp Off-Label Mtkg. & Sales Practices Litig.*, 590 F.Supp.2d 1282, 1287-88 (CD. Cal. 2008); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F.Supp.2d 1048, 1055 (E.D. Mo. 2002); *Infa-Lab, Inc. v. KDS Nail Int'l*, 2009 U.S. Dist. LEXIS 4509, at *10 (E.D. Cal. 2009) (dismissing state false advertising claims where complaint alleged that defendant's product "is labeled falsely and unlawfully, in direct violation of federal regulations"); *Pom Wonderful LLC v. The Coca Cola Co.*, 2009 U.S. Dist. LEXIS 65233. at *10-16 (C.D. Cal. Feb. 10, 2009) (disallowing false advertising claims focused on naming and labeling of the product. because the FDCA and accompanying regulations contained detailed regulations on other juice
(footnote continued)

Even if the FDA has not yet exercised its authority to establish standards for stereochemical nomenclature, it remains the administration appointed by Congress to speak on regulatory issues such as standards for the titling of ingredients and product labeling. That the FDA has yet to do so does not mean that Federal Courts are free to legislate in the arena. "The comprehensiveness of the legislative grant is not diminished, nor is the congressional intent to occupy the field rendered unclear, merely by reason of the regulatory agency's discretionary decision to exercise less than the total spectrum of regulatory power with which it was invested." *Mattoon v. City of Pittsfield*, 980 F.2d 1, 405 (1st Cir. 1992). Merck's own allegations acknowledge that Congress vested the FDA with authority over the entire regulatory scheme. As a result, the field has been occupied regardless of whether the FDA has made a regulatory decision.

Courts are ill-equipped to develop standards for matters not legal in nature. *United States ex rel. Joseph v. Cannon*, 642 F.2d 1373, 1379 (D.C. Cir. 1981). If this Court were to grant judgment in favor of Merck, it would effectively be creating federal common law dictating what is (and is not) appropriate stereochemical nomenclature for dietary supplements. Before doing so, the Court must decide whether it has the technical and scientific expertise necessary to create standards and rules to resolve this controversy justly or whether the matter should instead appropriately be left to the experts in the field and the FDA.

VI. MERCK IS NOT ENTITLED TO DAMAGES OR INJUNCTIVE RELIEF

A. Merck is Not Entitled to Actual Damages

Under Section 43(a), the trial courts have a great deal of discretion and latitude in awarding damages. To recover monetary damages, plaintiff must show actual damages that are causally related to consumer confusion or deception. *Mobius Management Systems, Inc. v. Fourth Dimension Software, Inc.*, 880 F.Supp. 1005, 1022 (S.D.N.Y. 1994); *Burndy Corp. v. Teledyne Industries, Inc.*, 748 F.2d 767, 771 (2d

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beverages, although not the product at issue); *Wyeth v. Sun Pharm. Indus., Ltd.*, 2010 U.S. Dist. LEXIS 18180, at *12 (E.D. Mich. Mar. 2, 2010) (dismissing a false advertising claim alleging that plaintiff had mislabeled its active ingredient on the ground that it is "solely the FDA's duty to investigate and prosecute allegations of misbranding or adulterating drugs").

Cir. 1984) ("A plaintiff who establishes false advertising in violation of § 43(a) of the Lanham Act will be entitled only to such damages as were caused by the violation."). Damages that can be incurred as a result of false advertising are lost profits from diverted sales, lost profits from sales made at reduced prices, the cost of completed corrective advertising to remedy the misrepresentation, and quantifiable harm to the plaintiff's goodwill. *Mobius Management Systems, Inc., supra,* 880 F.Supp. at 1023.

Although its First Amended Complaint seeks damages for items such as lost sales (¶58), loss of reputation (¶¶59, 62, 71, 93), and unspecified "damages" (¶¶64, 73, Prayer ¶F) caused by Gnosis' labeling, Merck has introduced no evidence support these bare damage allegations. In response to discovery, Merck has not pointed to a single sale lost to Gnosis and has refused to provide evidence related to its sales. (See, Katz Depo. 61:8-15.) As discussed herein, customers only turn to Gnosis after being terminated by Merck for failing to meet its minimum purchasing requirements or after Merck refuses to sell to them. Thus, these are not ***lost*** sales since Merck refused to sell to the customers in the first instance. Merck presented no evidence of reduced pricing, corrective advertising or any loss of goodwill or reputation in the industry.

B. Merck is Not Entitled to Gnosis' Profits

Instead of proving actual damages, "Merck will request from the Court, pursuant to 15 U.S.C. § 1117(a), three times Gnosis's profits. Merck will not seek its own lost profits." Merck's Second Supplemental Response to Special Interrogatory No. 8, p. 3. In the absence of actual damages, a defendant "will be ordered to account for its profits ***only if certain standards are met***." *Burndy Corp., supra,* 748 F.2d at 771 (emphasis added); 15 U.S.C. § 1117. It has been held in this circuit that an accounting of defendant's profits will be ordered in the Court's discretion only if the "defendant is unjustly enriched, if the plaintiff sustained damages from the infringement, or if an accounting is necessary to deter a willful infringer from doing so again." *Burndy Corp., supra,* 748 F.2d at 772; *W.E. Bassett Co. v. Revlon, Inc.,* 435 F.2d 656, 664 (2d Cir.1970) (quoting text).

In *Burndy Corp.,* the Second Circuit explained that the statutory remedy of an accounting of the defendant's profits is "rarely granted and appears to have been limited to situations in which the

defendant's profits represent unjust enrichment derived from diversion of business that clearly would otherwise have gone to the plaintiff, such as in instances where the defendant palmed off its goods as made by the plaintiff or otherwise infringed the plaintiff's rights rather than engaged simply in false advertising of the defendant's own product." 748 F.2d at 772. And, Merck bears the burden. *Ibid.*

The rationale for awarding defendant's profits simply does not apply here, where it is undisputed that Merck does not even sell the same product which Gnosis' allegedly mislabeled. As a result, Gnosis' customers could not have possibly purchased the 6RS Product from Merck and Merck cannot establish the requisite connection. This Court has already determined that Merck lacked any evidence that consumers believed they were purchasing Merck's 6S Product when they bought Gnosis' 6RS Product. Memorandum and Order of the Honorable Richard J. Sullivan, District Judge dated March 17, 2011, p. 9-10. Thus, even if Gnosis' labeling was confusing, it has already been determined that the consumers were not tricked into purchasing Gnosis' product instead of Merck's. Moreover, Merck already terminated many of Gnosis' customers for failing to satisfy its minimum purchasing requirements. And, Gnosis' 6RS Product is one third the price of Merck's 6S Product. Based on these facts, it cannot rationally be presumed that the Gnosis' customers would have instead paid three times the price but for their labeling confusion.

As it pertains to the other equitable considerations, Merck has not suffered any actual damages and Gnosis' choice of labeling was made in good faith. Merck's conduct reveals its true motives for bringing this action was to "get rich quick" at the expense of its competitor.[14] While Gnosis had some sales of its 6RS Product bearing the labeling at issue between March 2006 and March 2009, it cannot be said to have been ***unjustly*** enriched since its choice of labeling was technically accurate and since its customers were not confused by the abbreviations in any material manner.

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[14] Equitable considerations weigh against an award of Gnosis' profits because, despite Merck immediately threatening litigation, it did not file this action for more than a year. Thereafter, knowing it suffered no injury but had the option to elect the disgorgement of Gnosis' profits, Merck never sought a preliminary injunction in this case and instead allowed Gnosis to continue to earn profits. Accordingly, there exists no equitable basis to order an accounting of, or the disgorgement of, Gnosis' profits.

Finally, there is no support for the proposition that an accounting of Gnosis' profits should be ordered to deter future conduct since the labeling at issue has not been used for more than two years and since Gnosis' advertising and marketing campaigns have, since that time, been focused on its new labeling.[15]

C. There Exists No Basis for Injunctive Relief

To be entitled to injunctive relief, Merck must demonstrate that it will suffer irreparable harm absent the injunction. *Procter & Gamble Co., supra,* 574 F.Supp.2d at 347-348; *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 316 (2d Cir.1982). To do so, it must establish some logical causal connection between the alleged false advertising and its own sales position which rises above speculation. *Procter & Gamble Co., supra,* 574 F.Supp.2d at 348; *McNeilab, Inc. v. Am. Home Products Corp.,* 848 F.2d 34, 38 (2d Cir.1988); *Time Warner Cable, Inc., supra,* 497 F.3d at 161; *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir.1980). Merck can demonstrate no causal connection between its sales position and Gnosis' allegedly false advertising. The evidence establishes that Gnosis' sales dramatically increased after it discontinued use of the labeling at issue in 2009. (See, Ex. 1 hereto which charts the evidence regarding Gnosis' sales.) And, Merck has refused to produce evidence related to its own sales. As a result, Merck cannot satisfy its burden of demonstrating injury, let alone the requisite causal connection between that injury and the allegedly false advertising.

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[15] Merck inexplicably seeks the recovery of Gnosis' profits from 2006 ***up through the time of trial.*** Even if the Court determined that an award of Gnosis' profits was appropriate, there is no logical basis for awarding Merck profits which were earned after the allegedly confusing labeling ceased in March 2009. Notably, after Gnosis stopped using the labeling at issue and instead used the full chemical name in addition to the trade name, its profits increased exponentially. (See, Ex. 1) Merck is seeking to capitalize on Gnosis' success in the absence of any possible causal connection between those post-March 2009 profits and injury to either Merck or the public resulting from the labeling scheme. It would be wholly inequitable to award Merck a windfall by handing it Gnosis' profits earned using the very labeling scheme urged by Merck as correct. Thus, even assuming liability could somehow be proven, and the heightened standards for the recovery of profits satisfied, the profits awarded should appropriately be limited to those derived from sales of 6RS Product for the period of time in which Gnosis' products bore the labeling at issue, between March 2006 and March 2009.

Even if liability and standing could be established, injunctive relief is wholly unnecessary in light of Gnosis' change of labeling occurring more than two years ago.[16] And, Merck cannot be irreparably injured by Gnosis' sales of a product that Merck does not itself sell. *Sutton Cosmetics (P. R.) Inc. v. Lander Co.*, 455 F.2d 285, 289 (2d Cir. 1972).

Finally, Merck's delay in seeking injunctive relief weighs against a finding of irreparable harm. *Procter & Gamble Co.*, 574 F.Supp.2d at 353. Merck waited more than a year after first accusing Gnosis of patent infringement before commencing this action. Thereafter, Merck never sought a preliminary injunction. The more than five year delay weighs against a finding of irreparable harm.

Given that Merck has suffered no actual injury, and will suffer no injury in the future as a result of Gnosis' long-abandoned labeling, injunctive relief is moot under the circumstances and would only serve to reward Merck's anti-competitive conduct and embolden it to continue to use litigation as a vehicle for gaining a market advantage. The public interest would only be served through encouraging competition in the marketplace, not by allowing industry giants to dictate scientific nomenclature through the courts.

VII. GNOSIS IS ENTITLED TO AN AWARD OF ATTORNEYS' FEES AGAINST MERCK

In bringing this action and the various other actions filed against Gnosis' distributors and customers, Merck was not championing a righteous cause or protecting the public interest. Given that Merck suffered no actual damage, it was also not attempting to recover compensatory damages. Rather, it was the threat of emerging competition from Gnosis in a market where Merck previously enjoyed a monopoly that prompted Merck to initiate and maintain this litigation.

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[16] See, e.g., *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 39 U.S.P.Q.2d 1411 (5th Cir. 1996) (permanent injunction denied where defendant stopped using the challenged representations five years hence); Burndy Corp., supra, 748 F.2d at 772 ("permanent injunctive relief will be granted only upon proof of the likelihood that purchasers of the product may be misled in the future by the false advertising."); *American Exp. Travel Related Services Co., Inc. v. MasterCard Intern. Inc.*, 776 F.Supp. 787, 790-91 (S.D.N.Y. 1991) (A suit for injunctive relief is moot when the offending conduct ceases and the court finds "that there is no reasonable expectation that it will resume."); *Dunkin' Donuts Inc. v. Peter Romanofsky, Inc.*, (E.D.N.Y., Aug. 8, 2006, CV05-3200(SJ)(JMA)) 2006 WL 2433127 *6 (No threat of future consumer confusion where defendants abandoned the offending franchises a year prior).

An examination of the events leading up to this litigation reveal that immediately upon Gnosis' entry into the marketplace:

- Merck wasted no time in advancing hollow threats of patent litigation against Gnosis, its potential customers and its distributors. These threats alone cost Gnosis sales to potential customers who lacked the desire to engage in litigation with Merck.

- Thereafter, Merck waited more than a year to file this action for false advertising, asking this Court to determine that its marketing-based scientific naming convention was correct to the exclusion of all other recognized naming conventions.

- Even after being informed by an independent expert that Gnosis' use of the acronym at issue was technically correct, Merck vehemently maintained that Gnosis' labeling was literally false.

- Even after realizing that Gnosis' product was safe, Merck continued to claim that it presented a potential health risk to the public.

- Rather than commissioning a survey to determine that some appreciable percentage of customers were likely to be confused, Merck instead chose to further intimidate the very customers it threatened to sue, and the same customers it confused through its own inaccurate marketing campaign, by issuing deposition subpoenas and asking leading and suggestive questions. Even then, Merck was only able to elicit minimal and dubious evidence of confusion, falling fatally short of satisfying its burden.

- Merck never sought a preliminary injunction in this matter and instead allowed Gnosis to derive profits labeling that Merck alleged to be false. It realized early on that it would one day elect to recover those profits under the Lanham Act in light of Merck's knowledge that it truly suffered no damage. This conduct reveals Merck's true motives for bringing this action was to "get rich quick" at the expense of its competitor.

Section 35(a) of the Lanham Act states that, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 15 USCS § 1117(a). This clause has been interpreted to apply equally to prevailing defendants. The Second Circuit applies a bad faith analysis to determine when a Court, in its discretion, should appropriately award attorneys' fees to a prevailing defendant in a Lanham Act case. The Second Circuit's analysis centers on the plaintiff's motivation in bringing the case and the suit's objective legal merits." *Vital Pharmaceuticals, Inc. v. American Body Bldg. Products, LLC,* 510 F.Supp.2d 1043, 1048 (S.D. Fla. 2007) The focus is not only whether the action was initially brought in

bad faith and for an improper motive, but also whether the plaintiff's continued pursuit of the action was in bad faith. See, *Banff Ltd. v. Colberts Inc.,* 810 F. Supp. 79 (S.D.N.Y. 1992); *Spaulding Laboratories, Inc. v. Arizona Biological Control, Inc.,* 2008 WL 2227501 (C.D. Cal. 2008). As it pertains to this case, "exceptional circumstances" have been held to exist justifying an award of attorneys' fees to a prevailing defendant where the plaintiff's motivation in bringing suit is anti-competitive. Where, as here, the lawsuit presents nothing more than an effort to utilize the Lanham Act as a means of stifling legitimate emerging competition, rather than to protect a valid legal interest, attorneys' fees should properly be awarded to a prevailing defendant. See, *Vital Pharmaceuticals, Inc., supra,* 510 F.Supp.2d at 1051-1052. And, the fact that four of Merck's six claims managed to survive summary judgment does not absolve Merck from liability for attorneys' fees. "[T]he fact that plaintiff managed to bring these claims to trial is of little relevance as a general principle." *IMAF, S.p.A. v. J.C. Penney Co.,* 810 F.Supp. 96, 99 (S.D.N.Y.1992); *Diamond Supply Co. v. Prudential Paper Products Co.,* 589 F.Supp. 470, 475 (S.D.N.Y.1984); *Vital Pharmaceuticals, Inc., supra,* 510 F.Supp.2d at 1048.

In many respects, regardless of the outcome of this case, Merck has already won since its anti-competitive purpose for initiating this lawsuit has been largely realized.[17] And, since Gnosis changed its labeling more than two years ago, Merck has regained its monopoly over the scientific acronym L-5-MTHF, right or wrong. Thus, Merck does not even need to prevail at trial to accomplish its underlying anti-competitive goals. Given Merck's substantial resources, the costs associated with litigation are a small price to pay to eliminate, or at least financially devastate, its competition. But this Court has the equitable power and discretion to at least somewhat compensate Gnosis for being forced to defend itself for the past

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[17] In an email from Dr. Katz to Merck's distributor, Dr. Katz reveals Merck's true motives behind this litigation when she states: "Just for clarification: our goal is to stop AHD [Gnosis' distributor] from selling any quality of MTHF, including the racemic version." (DX108, Eprova0032041). Merck's litigation against AHD resulted in an agreement that AHD would no longer sell Gnosis' product. Merck's litigation against Gnosis' customers and threats of litigation against potential customers resulted in a sudden loss of interest from those parties in purchasing Gnosis' products (and a suspected agreement by at least one customer to instead purchase a significant quantity of product from Merck).

four years against Merck's meritless claims. Respectfully, Gnosis requests that the Court exercise its discretion and find that "exceptional" circumstances exist sufficient to justify an award of attorneys' fees in favor of Gnosis.

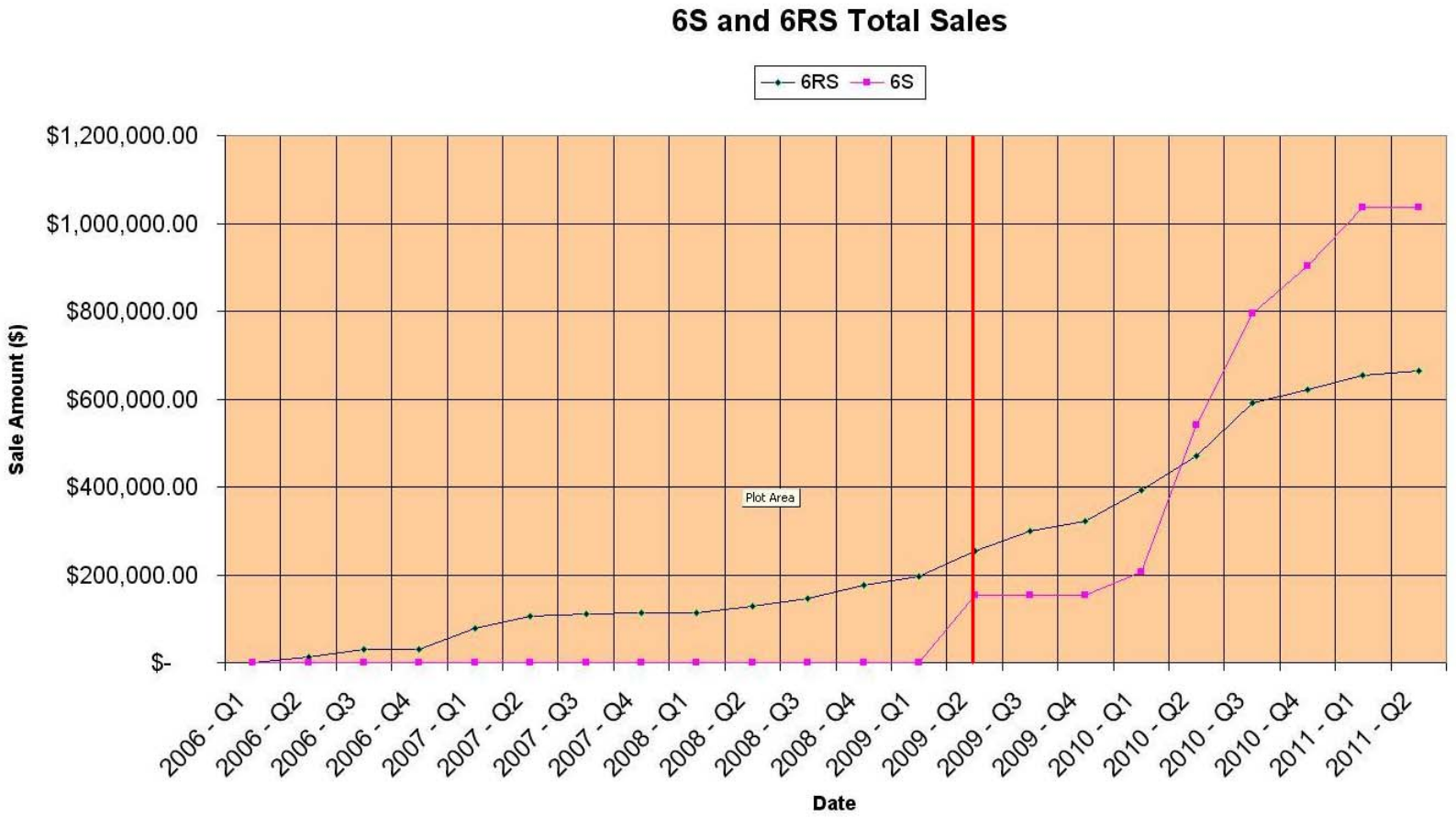
VIII. CONCLUSION

Based on the authorities and arguments set forth herein and the evidence will be introduced at trial, Defendants Gnosis S.p.A. and Gnosis BioResearch S.A. respectfully request that: This Court grant Judgment in their favor and against Plaintiff Merck & Cie (formerly Merck Eprova AG); that Merck take nothing by way of its First Amended Complaint; and that Defendants be awarded costs of suit and reasonable attorneys fees incurred in defending this action as permitted by law.

DATED: May 20, 2011

JULANDER, BROWN, BOLLARD & CHAPMAN

By: /s/ William D. Chapman
William D. Chapman
Attorney for Defendants



***** The red vertical line at Q2 of 2009 is when the L was dropped from all sales and marketing materials.**

MONTHLY SALES AVERAGES

	Amount Sold w/ L (36 months)		**Amount Sold w/o L (25 months)**	
Product	6RS	6S	6RS	6S
Total Sales	$ 196,400.00	$ -	$ 467,893.69	$ 1,037,137.25
Total Months	36	36	25	25
Sales Per Month	**$ 5,455.56**	$ -	**$ 18,715.75**	$ 41,485.49

EXHIBIT 1